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# Medical Policy

# **Surgical and Debulking Treatments for Lymphedema**

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Policy Number: 037

BCBSA Reference Number: N/A

NCD/LCD: N/A

#### **Related Policies**

None

# **Policy**

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

## Lymph node transplant<sup>1</sup>

Lymph node transplant may be considered MEDICALLY NECESSARY when criteria 1-4 are met:

- 1. Patient meets **ALL** of the following diagnostic criteria:
  - a. Signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist **AND** a diagnosis of stage ≥ II lymphedema (ISL)\*
  - b. At least **one** of the following positive quantitative measurements:
    - i. For unilateral disease
      - Volumetry differential (circumferential measurements and/or perometry differential) >10% (if affected extremity dominant extremity) or >7% (affected extremity is non-dominant extremity), OR
      - Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), OR a dermal back flow pattern
    - ii. For bilateral disease
      - lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), OR dermal back flow.
- 2. Patient meets **ALL** of the following lymph node transplant eligibility criteria:

- a. Patient has BMI ≤ 35kg/m<sup>2</sup>
- b. Patient has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months
  - i. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet)
     AND any of the following treatment modalities: manual lymphatic drainage, complete decongestive therapy, use of pneumatic compression pump, targeted exercises for lymphedema treatment
- c. Patient has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
- 3. Patient has **NONE** of the following:
  - Transient lymphedema: any swelling that meets threshold for lymphedema criteria and occurs up to six months post last oncologic treatment
  - b. Lipidema without lymphatic dysfuction
  - c. Any of the following uncontrolled comorbidities:
    - i. Venous disease (DVT, superior vena cava syndrome)
    - ii. Congestive heart failure (CHF)
    - iii. Medication-induced swelling
    - iv. Liver disease including but not limited to cirrhosis, hypoproteinemia
    - v. Nephropathy including end-stage renal disease
  - d. Pregnancy
  - e. Dye anaphylaxis
  - f. Active infection of the affected extremity (cellulitis/erysipelas).
- 4. Surgery must be performed by a certified lymphedema center of excellence.

Lymph node transplant is considered **INVESTIGATIONAL** if the above criteria are not met.

## Lymphovenous bypass<sup>1</sup>

Lymphovenous bypass may be considered **MEDICALLY NECESSARY** when criteria 1-4 are met:

- 1. Patient meets **ALL** of the following diagnostic criteria:
  - a. Signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist **AND** a diagnosis of stage ≥ I lymphedema (ISL)\*
  - b. At least one of the following positive quantitative measurements:
    - i. For unilateral disease
      - Volumetry differential (circumferential measurements and/or perometry differential) >10% (if affected extremity dominant extremity) or >7% (affected extremity is non-dominant extremity), OR
      - 2. Bioimpedance (L-Dex) differential of at least 10 units, OR
      - Lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), OR dermal back flow
    - ii. For bilateral disease
      - lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), OR dermal back flow.
- 2. Patient meets **ALL** of the following lymph node transplant eligibility criteria
  - a. Patient has BMI ≤ 35kg/m<sup>2</sup>
  - b. ICG lymphangiography findings demonstrate the presence of lymphatic channels
  - c. Patient has completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months
    - i. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet)

      AND any of the following treatment modalities: manual lymphatic drainage, complete

decongestive therapy, use of pneumatic compression pump, targeted exercises for lymphedema treatment

- d. Patient has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
- 3. Patient has **NONE** of the following:
  - a. Transient lymphedema: any swelling that meets threshold for lymphedema criteria and occurs up to six months post last oncologic treatment
  - b. Lipidema without lymphatic dysfuction
  - c. Any of the following uncontrolled comorbidities:
    - i. Venous disease (DVT, superior vena cava syndrome)
    - ii. Congestive heart failure (CHF)
    - iii. Medication-induced swelling
    - iv. Liver disease including but not limited to cirrhosis, hypoproteinemia
    - v. Nephropathy including end-stage renal disease
  - d. Pregnancy
  - e. Dye anaphylaxis
  - f. Active infection of the affected extremity (cellulitis/erysipelas).
- 4. Surgery must be performed by a certified lymphedema center of excellence.

Lymphovenous bypass for the prevention of lymphedema is considered **INVESTIGATIONAL**.

Lymphovenous bypass is considered **INVESTIGATIONAL** if the above criteria are not met.

#### Debulking of a limb<sup>1</sup>

Debulking of a limb impacted by lymphedema may be considered <u>MEDICALLY NECESSARY</u> when criteria 1-4 are met:

- 1. Patient meets to following diagnostic criteria:
  - a. Signs and symptoms consistent with lymphedema as determined by a certified lymphedema therapist **AND** a diagnosis of stage ≥ II lymphedema (ISL)\*
  - b. At least one of the following positive quantitative measurements:
    - i. For unilateral disease
      - 1. Volumetry differential (circumferential measurements and/or perometry differential) >10% (if affected extremity dominant extremity) or >7% (affected extremity is non-dominant extremity), **OR**
      - 2. bioimpedance (L-Dex) differential of at least 10 units
    - ii. For bilateral disease
      - lymphoscintigraphy findings must show a minimum of a one-hour delayed transit time to first-level lymph nodes, axillary lymph nodes (upper extremity lymphedema) or inguinal lymph nodes (lower extremity lymphedema), OR dermal back flow.
- 2. Debulking eligibility criteria
  - a. Patient has BMI ≤ 35kg/m²
  - b. Patient has MRI imaging findings consistent with moderate to severe fat hypertrophy
  - c. Patient must have completed a course of conservative treatment defined as lymphedema therapy for a minimum of 20 hours/week for 6 months
    - i. Lymphedema therapy includes compression therapy (bandaging/garment/gauntlet)

      AND any of the following treatment modalities: manual lymphatic drainage, complete decongestive therapy, use of pneumatic
    - ii. compression pump, targeted exercises for lymphedema treatment
  - d. Patient has demonstrated the ability to tolerate post-surgical compression therapy and physical therapy sessions per treating lymphedema provider.
- 3. Patient has **NONE** of the following:

- a. Transient lymphedema: any swelling that meets threshold for lymphedema criteria and occurs up to six months post last oncologic treatment
- b. Lipidema without lymphatic dysfuction
- c. Any of the following uncontrolled comorbidities:
  - i. Venous disease (DVT, superior vena cava syndrome)
  - ii. Congestive heart failure (CHF)
  - iii. Medication-induced swelling
  - iv. Liver disease including but not limited to cirrhosis, hypoproteinemia
  - v. Nephropathy including end-stage renal disease
- d. Pregnancy
- e. Dye anaphylaxis
- f. Active infection of the affected extremity (cellulitis/erysipelas).
- 4. Surgery **must be performed** by a <u>certified lymphedema center of excellence</u>.

Debulking of a limb is considered **INVESTIGATIONAL** if the above criteria are not met.

\* Table 1 lists International Society of Lymphology guidance for staging lymphedema based on "softness" or "firmness" of the limb and the changes with an elevation of the limb.

Table 1. Recommendations for Staging Lymphedema Stage	Description
Stage 0 (subclinical)	Swelling is not evident and most patients are asymptomatic despite impaired lymphatic transport
Stage I (mild)	Accumulation of fluid that subsides (usually within 24 hours) with limb elevation; soft edema that may pit, without evidence of dermal fibrosis
Stage II (moderate)	Does not resolve with limb elevation alone; limb may no longer pit on examination
Stage III (severe)	Lymphostatic elephantiasis; pitting can be absent; skin has trophic changes

#### **Prior Authorization Information**

#### Inpatient

• For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

#### Requesting Prior Authorization Using Authorization Manager

Providers will need to use <u>Authorization Manager</u> to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the service request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, not the billing group.

#### **Authorization Manager Resources**

Refer to our <u>Authorization Manager</u> page for tips, guides, and video demonstrations.

## **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

## **CPT Codes**

CPT	
codes:	Code Description
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

# **ICD-10 Procedure Codes**

	ICD-10 Procedure Codes	
ICD-10-		
PCS .		
procedure		
codes:	Code Description	
07Q10ZZ	Repair Right Neck Lymphatic, Open Approach	
07Q13ZZ	Repair Right Neck Lymphatic, Percutaneous Approach	
07Q14ZZ	Repair Right Neck Lymphatic, Percutaneous Endoscopic Approach	
07Q18ZZ	Repair Right Neck Lymphatic, Via Natural or Artificial Opening Endoscopic Approach	
07Q20ZZ	Repair Left Neck Lymphatic, Open Approach	
07Q23ZZ	Repair Left Neck Lymphatic, Percutaneous Approach	
07Q24ZZ	Repair Left Neck Lymphatic, Percutaneous Endoscopic Approach	
07Q28ZZ	Repair Left Neck Lymphatic, Via Natural or Artificial Opening Endoscopic Approach	
07Q30ZZ	Repair Right Upper Extremity Lymphatic, Open Approach	
07Q33ZZ	Repair Right Upper Extremity Lymphatic, Percutaneous Approach	
07Q34ZZ	Repair Right Upper Extremity Lymphatic, Percutaneous Endoscopic Approach	
07Q38ZZ	Repair Right Upper Extremity Lymphatic, Via Natural or Artificial Opening Endoscopic Approach	
07Q40ZZ	Repair Left Upper Extremity Lymphatic, Open Approach	
07Q43ZZ	Repair Left Upper Extremity Lymphatic, Percutaneous Approach	
07Q44ZZ	Repair Left Upper Extremity Lymphatic, Percutaneous Endoscopic Approach	
0704977	Repair Left Upper Extremity Lymphatic, Via Natural or Artificial Opening Endoscopic	
07Q48ZZ	Approach	
07Q50ZZ	Repair Right Axillary Lymphatic, Open Approach	
07Q53ZZ	Repair Right Axillary Lymphatic, Percutaneous Approach	
07Q54ZZ	Repair Right Axillary Lymphatic, Percutaneous Endoscopic Approach	
07Q58ZZ	Repair Right Axillary Lymphatic, Via Natural or Artificial Opening Endoscopic Approach	
07Q60ZZ	Repair Left Axillary Lymphatic, Open Approach	

07Q63ZZ	Repair Left Axillary Lymphatic, Percutaneous Approach
07Q64ZZ	Repair Left Axillary Lymphatic, Percutaneous Endoscopic Approach
07Q68ZZ	Repair Left Axillary Lymphatic, Via Natural or Artificial Opening Endoscopic Approach
07Q80ZZ	Repair Right Internal Mammary Lymphatic, Open Approach
07Q83ZZ	Repair Right Internal Mammary Lymphatic, Percutaneous Approach
07Q84ZZ	Repair Right Internal Mammary Lymphatic, Percutaneous Endoscopic Approach
07Q88ZZ	Repair Right Internal Mammary Lymphatic, Via Natural or Artificial Opening Endoscopic Approach
07Q90ZZ	Repair Left Internal Mammary Lymphatic, Open Approach
07Q93ZZ	Repair Left Internal Mammary Lymphatic, Percutaneous Approach
07Q94ZZ	Repair Left Internal Mammary Lymphatic, Percutaneous Endoscopic Approach
07Q98ZZ	Repair Left Internal Mammary Lymphatic, Via Natural or Artificial Opening Endoscopic Approach

# **Description**

Lymphedema is a chronic condition caused by accumulation of subcutaneous fluid and fat in body tissue. It can lead to pain, disfigurement, predisposition to infection, decreased patient quality of life, and even malignant transformation. Recurrent episodes of infection (cellulitis) can cause further lymphatic damage and are associated with increased patient morbidity and mortality. Lymphedema can be either primary or secondary in nature. Primary (congenital) lymphedema is rarer and results from congenital lymphatic dysfunction. Secondary lymphedema is more common and often occurs after injury or insult to the lymphatic system (infection, surgery, removal of lymph nodes). Any part of the body can be affected; however, in the United States, breast cancer-related lymphedema (involving the upper extremities) prevails. The risk of lymphedema is increased by factors such as increased number of nodes removed during axillary lymph node dissection (ALND), radiation, and elevated body mass index (BMI).

Treatment for lymphedema has been largely palliative in nature and aimed towards preventing disease progression. Patient education regarding skin hygiene to prevent infection and the importance of maintaining a healthy body weight (via dieting and exercise) are two central tenets of disease management. Limb elevation is often advised to decrease limb swelling. Conservative therapy includes manual lymphatic drainage (MLD), which involves movement of the lymph away from the affected limb (where there are obstructions of lymph/lymph nodes) by a certified therapist. Compression garments are often used to decrease limb girth. Patients can also be instructed to perform MLD independently. Decongestive therapy is a combination of both MLD, compressive bandaging, skin care, and other conservative management modalities. Pneumatic pumps can also be used. These devices are designed to force excess lymph fluid out of the effected limb and into central body circulation. Pneumatic pumps can be single or multichambered and have the potential to be programmed to apply a fixed pressure.

When conservative treatment fails, surgical intervention may be considered. Procedures can be either physiologic or ablative. Physiologic procedures help restore lymphatic flow and include lymphovenous bypass and vascularized lymph node transplant. Although shown to demonstrate physiological changes on lymphoscintigraphy, ablative procedures for treatment of lymphedema include debulking.

Vascularized lymph node transplant is a surgical procedure where autologous healthy tissue and lymph nodes are transferred to the affected limb. Different theories exist regarding the mechanism of action of VLNT. One theory posits that the transplanted lymph nodes produce growth factors to produce and bridge lymphatic pathways. Another theory proposes that the VLNT acts as a pump to move lymphatic fluid away from the affected limb and into central circulation. Thus far, despite its treatment success, no definitive mechanism has been elucidated. This treatment option has been used for patients with BCRL and others with chronic lymphedema of both the upper and lower extremity. There are various donor sites (where the autologous tissue and lymph nodes are harvested) that have been described including the groin, omentum, submental region, supraclavicular region, and thoracic area. Recipient sites (where the autologous tissue and lymph nodes are transferred) also vary and include the axilla, elbow, wrist, ankle, groin, and knee.

Complications include donor site lymphedema, seroma, lymphocele, donor-site pain/paresthesia, and infection. These vary depending on area of intervention (harvest), harvest technique, and transfer location.

Lymphovenous anastomosis or lymphovenous bypass is a physiologic surgical procedure for the treatment of primary and/or secondary lymphedema. In this procedure, lymphatic fluid is diverted into the venous system through one or more anastomoses of lymphatic channels to venous drainage. This would create a physiological bypass of lymphatic fluid before it reached an area of obstruction in the affected extremity. In patients with chronic lymphedema, the accumulation of lymphatic fluid increases lymphatic pressure and causes dilation of the vessel. The pressure differential promotes flow from the lymphatic vessel to the recipient vein. There have been multiple techniques described. Compared to vascularized lymph node transplant, this surgical option has been associated with fewer risks and a is considered less invasive.

Liposuction for lymphedema is usually performed under general anesthesia. Small incisions in the affected extremity(ies) are made and excess tissue is removed by vacuum aspiration. Liposuction is generally performed around the entire circumference of the limb and compression bandaging is applied post-operatively to control bleeding and limit post-operative swelling. Antibiotics are commonly prescribed. To achieve ultimate volume reduction, patients must wear a garment, which often is custom-fitted to the extremity. Patients may need to return for new garment fitting throughout the first year until a stable limb volume is achieved.

The Lymphatic Education & Research Network (LE&RN) is a non-profit organization dedicated to education, research and advocacy related to lymphatic diseases (LD). LE&RN has designed an international standard for best practice multi-disciplinary care in the management of LD and has a certification process to designate LD Centers of Excellence. The criteria include diagnostic capabilities, imaging capabilities, conservative management services, assessment tools and surgical capabilities.

## **Summary**

For patients with lymphedema who undergo debulking procedures, the evidence includes one systematic review and meta-analysis, one prospective cohort study, one retrospective review, and two case series. Three studies involve a BCRL patient-population. The systematic review and meta-analysis by Carl et al. include 105 patients with both upper extremity (n=99) and lower extremity (n=9) lymphedema. Liposuction is the technique used in three studies and suction-assisted lipectomy is used in one study. All four studies report on volume reduction (using circumferential measurements and water displacement) compared to the contralateral side. On meta-analysis, the weighted excess volume reduction in the study by Carl et al. was 96.6% (95%CI: 86.2-107). Patients were told to adhere to a post-operative compression regimen. ISL staging was used in two studies and patients undergoing debulking procedures were at least stage II. Three studies reported on quality of life measures and showed improvement in the personally important activities index, reduced anxiety and improved sense of wellbeing. The SF-36 was also used to evaluate physical function improvement in one study. Follow up time ranged from a minimum of 12 months to 38.4 months. In a study by Lee et al. in an exclusive breast cancer patient population (122/130 receiving adjuvant radiation), a 97% decrease was found in upper extremity girth. Although there was an overall decreased incidence of infection (erysipelas) observed in this cohort, de novo infection did occur in 6 of 56 patients who had never had a prior occurrence. Decrease in infection was observed across all studies assessing this outcome. In the study by Lamprou et al, cellulitis incidence decreased from a mean of 6 attacks/year to 0.3 attacks/year after surgical intervention. The overall incidence of complications was low. In one study by Brorson et al, patients who underwent liposuction and used post-operative compression were compared to patients receiving compression only (control). Patients receiving compression had decreased volume changes compared to the intervention group and scored comparatively worse on all quality of life and functional indices used (VAS, HAD, NHP, PSG).

Available literature for VLNT includes 3 systematic reviews and meta-analyses, 1 systematic review, 1 randomized control trial, and one cross-sectional study. Studies report on patients with both upper and lower extremity lymphedema. Varying types of flaps and flap harvesting techniques were described. Mean overall reduction in limb volume was observed in all studies assessing this outcome. We acknowledge that there was heterogeneity in measurement modality. Notable findings included reduction in infection incidence, functional improvement, and improved quality of life measures. In the largest study

by Ozturk et al including 305 patients, there was no incidence of donor-site lymphedema. In the RCT conducted by Dionyssiou et al., the authors conclude that improvement in the abovementioned 3 parameters suggest clear superiority of surgical intervention over conservative management. In three studies, the authors reported on reduction in hours of therapy. In these studies, 78%, 60%, and 53% of patients, respectively, were able to discontinue therapy after undergoing VLNT. Subjective improvement was observed in 84%-100% of all patients undergoing this procedure.

Available literature evaluating lymphovenous bypass as a surgical intervention for the treatment of chronic lymphedema includes three systematic reviews, two literature reviews, and one prospective cohort study. A total of 6066 patients were included in analysis; with some existing overlap between systematic and literature reviews. Studies demonstrated a consistent trend in reduction of limb volume and circumferential measurements. Furthermore, patient quality of life was exclusively assessed in the study by Salgarello et al. which utilized a validated tool, the LYMQOL in patients at multiple time points after LVA. The study supports that LVA improved health-related quality of life in patients with both UE and LE lymphedema across all four LYMQOL domains, and overall quality of life. In the systematic review by Scaglioni et al, 50-100% of all patients reported symptomatic reduction; however, only one study used a validated tool (SF-36). The study by Leung et al. consisted exclusively of a BCRL patient population and found an overall 26% mean volumetric reduction at one year. The excess volume reduction ranged from 2% to 61%. Infection was a commonly reported outcome and all studies reported a mean decrease in the number of infections patients reported post-operatively. Furthermore, 56.3% to 85% of patients were able to discontinue or decrease the class of compression post-operatively. One study by Chang et al. supports that volumetric reduction may be more robust in patients with earlier staged lymphedema (MD I-II) who had a 61% overall reduction compared to those with later-stage lymphedema (MD III-IV) who had a mean 17% reduction. Differences in assessment modality compromised the ability to compare results across studies. However, consistent modes of limb assessments were used pre-operatively and post-operatively in all studies and often consisted of either circumferential measurements or water displacement. In studies where LVA with compression was compared to compression only, more pronounced objective and subjective improvement was seen in the LVA+compression group. Complications were infrequently reported across studies. Basta et al. reported an overall rate of infection of 3.9% and lymphorrhea of 4.1%.

Primary outcomes for the above surgical procedures include change in limb circumference (compared to the contralateral extremity), symptom reduction, patient-reported quality of life, and complications. The current available evidence in conjunction with expert opinion demonstrates improved clinical outcomes for patients who are appropriately diagnosed with lymphatic disease and who do not respond to conservative treatments.

## **Policy History**

Date	Action
3/2025	Policy clarified. Prior Authorization Using Authorization Manager information added.
6/2024	Policy clarified. Statement added to indicate lymphovenous bypass is investigational
	for prevention of lymphedema.
2/2022	Added link to lymphedema centers of excellence.
11/2021	Policy clarified. Criteria pertaining to Bioimpedance (L-Dex) differential of at least 10
	units was removed. Policy intent is unchanged.
5/2019	New medical policy describing medically necessary and investigational indications.
	Effective 5/15/2019.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

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## **Endnotes**

<sup>1</sup> Based on expert opinion